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| 10/553,661 | 10/17/2005 | Kenneth Kao | 50680-6 /slr | 4668 |
| 7390 7590 12/17/2008 SMART & BIGGAR P.O. BOX 2999, STATION D 900-55 METCALFE STREET OTTAWA, ON K1P5Y6 CANADA | | | | |
| EXAMINER | | | | |
| GUSSOW, ANNE | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,661

Applicant(s)

KAO ET AL.

Examiner

ANNE M. GUSSOW

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 8, 10, 57-59, 61, 65-67 and 70-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 4, 8, 57-59, 61, 70-77 and 79-82 is/are allowed.
- 6) ☒ Claim(s) 10, 65-67, 78 and 83-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 19, 2008 has been entered.
2. Claims 1, 2, 4, 8, 10, 57-59, 61, 65-67, and 70-89 are under examination.
3. The following Office Action contains NEW GROUNDS of Rejection.

Rejections Withdrawn

4. The rejection of claims 8, 10, 59, 61, 65-67, 70, 71, 75, and 78-89 under 35 U.S.C. 112, second paragraph as being indefinite is withdrawn in view of applicant's amendment to the claims filed September 29, 2008.

Rejections Maintained/ NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Isogai, et al. (US PAT 6,943,241, filed March 25, 2002, as cited on the PTO-892 mailed July 31, 2008).

The claims recite an antibody or fragment thereof that binds specifically to hPygo2 protein in the region set forth as amino acids 89-328 of SEQ ID NO: 2, wherein the antibody is a monoclonal antibody or fragment thereof, wherein the antibody is a polyclonal antibody.

Isogai, et al. teach a protein that is identical to the amino acids 160-406 of the instant SEQ ID No. 2 (see sequence alignment in Office Action appendix mailed July 31, 2008). Isogai, et al. teach monoclonal and polyclonal antibodies that bind to the polypeptide for detection, diagnosis or protein purification (column 38 lines 30-57).

In response to applicant's arguments regarding the Isogai, et al. sequence, the product of the claim, an antibody that binds to amino acids 89-328 of hPygo2, is defined in terms of a laboratory designation rather than by physical characteristics, structure or even the process by which the product is prepared. Consequently, comparison of this product with the prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Thus a lesser burden of proof is required to make out a case of anticipation for a product claimed in terms of a laboratory designation than when claimed in conventional fashion by its physical characteristics, structure or even in terms of the process by which it is made.

Therefore, it is the Examiner's position that Isogai, et al. have produced antibodies that are directed to the same antigen that the claimed antibodies bind. One of ordinary skill in the art would reasonably conclude that Isogai's antibody also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Isogai, et al. have produced antibodies that are identical to the claimed antibody. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Isogai, et al., the burden of proof is upon the Applicants to show an unobvious

distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Since the sequence of the instant hPygo2 and the sequence of Isogai, et al. share a large region of identity (an overlap of 168 amino acid residues, 160-328), the antibodies of Isogai, et al. would necessarily cross react with the instant hPygo2 and all the limitations of the claims have been met.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The rejection of claims 10, 65-67, 78, and 83-89 under 35 U.S.C. 103(a) as being unpatentable over Isogai, et al. (US PAT 6943241, filed March 25, 2002) in view of Kennedy (US PG PUB 2001/0016651, filed January 31, 2001) is maintained.

Applicant's response filed November 19, 2008 has been carefully considered but is deemed not to be persuasive. The response states that Claims 10 and 87, and claims dependent thereon, recite an antibody or fragment thereof that binds specifically to hPygo2 protein in the region set forth as amino acids 89-328 of SEQ ID NO: 2. In the previous response, we explained that antibodies to this region are expected to be specific to hPygo2 because this region of hPygo2 excludes the domains NHD and PHD, which are conserved domains (see page 4 lines 1-8 of the specification). In contrast, Isogai's SEQ ID NO: 1998 includes the entire PHD domain (which extends from amino acids 329 to 385 of SEQ ID NO: 2; see Figure 1 of the specification).

Accordingly, Isogai's antibodies would not be expected to bind specifically to hPygo2 as required by the claims (see applicant's response filed September 29, 2008 pages 7-8).

In response to this argument, as set forth above, the product of the claim, an antibody that binds to amino acids 89-328 of hPygo2, is defined in terms of a laboratory designation rather than by physical characteristics, structure or even the process by which the product is prepared. Consequently, comparison of this product with the prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Thus a lesser burden of proof is required to make out a case of anticipation for a product claimed in terms of a laboratory designation than when claimed in conventional fashion by its physical characteristics, structure or even in terms of the process by which it is made.

Therefore, it is the Examiner's position that Isogai, et al. have produced antibodies that are directed to the same antigen that the claimed antibodies bind. One of ordinary skill in the art would reasonably conclude that Isogai's antibody also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Isogai, et al. have produced antibodies that are identical to the claimed antibody. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Isogai, et al., the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Thus, since the sequence of the instant hPygo2 and the sequence of Isogai, et al. share a large region of identity (an overlap of 168 amino acid residues, 160-328), the antibodies of Isogai, et al. would necessarily cross react with the instant hPygo2.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

9. Claims 1, 2, 4, 8, 57-59, 61, 70-77, and 79-82 appear to be in condition for allowance.

Claims 10, 65-67, 78, and 83-89 are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
December 15, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643